

HÖLTERS & ELSING  
RECHTSANWÄLTE

HÖLTERS & ELSING, FREIHERR-VOM-STEIN-STR. 24-26, D-60323 FRANKFURT

**Per Einschreiben/By Registered Mail**

Mr. Detlev Goj  
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11. Oktober 2006

**Collingwood Pharmaceuticals, Inc. / Ovamed GmbH -  
Concerns raised in your e-mail of September 1, 2006**

Dear Mr. Goj,

We are writing to you on behalf of our clients, Collingwood Pharmaceuticals, Inc. ("Collingwood") and Paramount BioSciences, LLC ("Paramount"), in response to your e-mail of September 1, 2006 regarding certain aspects of the business relationship between Collingwood and Ovamed GmbH ("Ovamed") as it relates to the development of Trichuris suis ova ("TSO").

As you know, Collingwood is a party to the Manufacturing and Supply Agreement by and between Collingwood and Ovamed, dated March 29, 2006 (the "MSA"), and the Exclusive Sublicense Agreement by and between Collingwood and Ovamed, effective as of December 12, 2005 (the "SLA" and together with the MSA, the "Contracts").

Since you have raised some concerns regarding the existence of Collingwood and the authorization of the persons representing it, we would like to confirm at the outset of this letter that Collingwood is a duly established and existing corporation under the laws of the State of Delaware and an affiliate of Paramount. In advance of the establishment of a permanent development team at Collingwood, Paramount, as you are aware, appointed Ms.

Kim Weinberger as the project team leader for its San Diego-based TSO development team (the "TSO Development Team"). The TSO Development Team is currently conducting all of the strategic and tactical functions regarding the development of TSO and will continue to support the TSO development project and to work cooperatively with Ovamed in areas of mutual interest and concern. You have been provided with Ms. Weinberger's contact details and instructed to contact her with any issues or concerns arising under the Contracts. As per the notice provisions of the Contracts, you are also welcome to direct your correspondence to Mr. Frank Taffy (under the MSA) and Mr. Jay Lobell, President of Collingwood (under the SLA). We trust this information resolves any concerns you may have had regarding the existence of Collingwood or the authorization of the persons representing it.

In this context, however, we have concerns with respect to the correct name and legal form of Ovamed as well as concerns with respect to the proper identity of the managing directors representing the company. In the License Agreement by and between Ovamed and the University of Iowa Research Foundation ("UIRF"), dated December 8, 2005 (the "License Agreement"), "OvaMed GmbH" is the counterparty. However, the counterparty to the SLA is "Ovamed GmbH & Co. KG", while the counterparty to the MSA is "Ovamed GmbH". Additionally, both the License Agreement as well as the SLA were signed by you in your capacity as "CEO". According to a current excerpt of the commercial register, Mr. Frank Goj is registered as one of two managing directors of Ovamed GmbH; Ovamed GmbH & Co KG, however, is not registered at all. On behalf of our client, we would be grateful if you could explain and clarify the situation with respect to the existence of the company and to its managing directors.

Further to your e-mail of September 1, 2006 and in order to address the concerns you have raised, we have been instructed by Collingwood to review the Contracts and related correspondence and written information. Having evaluated the Contracts under German Law and assessed the related correspondence and written information, we express our client's position in the above matter as follows:

I. No Violation of the Contracts or Breach of Good Faith by Collingwood

We respectfully cannot agree, for numerous reasons, with your opinion (expressed under the first item of your e-mail) that an attempt of Collingwood to obtain TSO from sources other than Ovamed must be regarded as a violation of the Contracts and is a breach of the principle of good faith according to Section 242 of the German civil code ("BGB").

1. Non-Exclusivity of the MSA

a) No Explicit Exclusivity Provisions

The MSA contains no explicit provisions with respect to exclusivity that justify the statement that Ovamed must be the sole supplier of TSO. If the parties had intended to enter into the MSA on an exclusive basis, they could, and would, have stated this explicitly in the MSA (just as this was done in your contractual arrangements with Dr. Falk Pharma GmbH ("Dr. Falk"), see subpart c) below).

b) Textual Evidence of Non-Exclusivity in Section 8.2.2 of the MSA

Quite the opposite, the language in the MSA makes plain that the supply arrangement between Ovamed and Collingwood is *non-exclusive*. For example, Section 8.2.2 of the MSA provides that in the event Ovamed fails to meet certain supply obligations, Collingwood may terminate the MSA upon notice of such failure and certain other conditions if Collingwood "has not, at the time, developed a *commercial second source* ...". This reference to Collingwood being permitted to develop "a commercial second source" indicates that the parties always expected Collingwood to develop a second source for the delivery of TSO and makes it more than clear that the parties did not view the manufacturing relationship as an exclusive one.

c) German Anti-Trust and Competition Law

Without going into extensive detail on this issue, we would like to remind you of the legal enforceability of exclusivity clauses under applicable anti-trust and competition laws. Because exclusivity clauses tend to restrict competition, they must be considered exceptional and they cannot be manufactured and forced into an agreement which plainly contains none.

d) Negotiation of the Contracts

Because the Contracts are clear on their face, no resort is necessary to matters outside the Contracts. It also is clear, however, that at the time the Contracts were negotiated and drafted, there was no discussion between the parties as to possible exclusivity of the MSA. Similarly, the Term Sheet by and between Paramount and Ovamed, dated September 16, 2005 (the "Term Sheet"), which was drafted preliminarily in respect of the SLA and which is governed by the laws of the State of New York, is silent as to the issue of exclusivity under the MSA. In particular, paragraph 9 of the Term Sheet states merely the undertaking of the parties to negotiate a separate MSA; it contains no further provisions that Collingwood shall purchase the TSO from Ovamed exclusively.

e) Exclusive Agreement with Dr. Falk Pharma

The Development, Manufacturing and Commercialization Agreement between Ovamed (formerly known as Biocure GmbH) and Dr. Falk, dated January 9, 2004 (the "Dr. Falk Agreement"), relates to the development, manufacturing and commercialization of TSO and addresses subject matters similar to the ones in the Contracts. Articles 11 and 13 of the Dr. Falk Agreement both make explicit reference to the fact that Ovamed shall be the exclusive supplier of licensed products to Dr. Falk. In particular, Article 13 ("Exclusive supply of Licensed Products") states that Dr. Falk "shall exclusively purchase the Licensed Products from" Ovamed.

The Dr. Falk Agreement demonstrates that Ovamed is well-aware of the necessity of an explicit exclusivity clause in contracts where the parties intend for there to be exclusive dealings. Given the similarity of scope and product in the Dr. Falk Agreement and the Contracts, it is clear that Ovamed did not inadvertently fail to include an explicit exclusivity clause into the MSA with Collingwood; rather, this circumstance reflects the parties' agreement that the MSA would be *non-exclusive*.

2. No Breach of Good Faith

Under these circumstances, Section 242 of the BGB would be relevant only to vindicate the parties' agreement, which is accurately reflected in the Contracts. Far from vindicating the parties' agreement, Ovamed's invocation of Section 242 of the BGB seeks to eviscerate it. Because the MSA contains no exclusivity restrictions—indeed, it states that Collingwood is permitted to develop "a commercial second source"—any efforts by Collingwood to establish a second source for the supply of TSO would be in full conformity with the Contracts. By definition, it would not be a breach of the principle of good faith according to Section 242 of the BGB. Furthermore, though it would fully within its rights to do so, please be aware that Collingwood has, until now, not contractually engaged a second source for the supply of TSO. Rather, Collingwood has taken the prudent measure of exploring the market to determine what potential opportunities exist for the development of a second source for the supply of TSO.

II. Breach of the MSA by Ovamed

The irony in Ovamed's assertions against Collingwood is that Ovamed, not Collingwood, has acted in contravention of the Contracts. Based on recent communications between Collingwood and Ovamed, and due to Collingwood's urgent need for TSO meeting CGMP requirements, we would like to point out the serious concerns of Collingwood in respect of Ovamed's compliance with its contractual obligations.

1. Ovamed's Inability to Supply TSO Meeting CGMP Requirements

Over a period of several telephone conferences, subsequent e-mail correspondence and oral communication with Ovamed, Collingwood has repeatedly attempted to obtain information as to the availability of TSO meeting CGMP requirements. As you know, Collingwood requires TSO meeting CGMP requirements for both its Phase 2a Crohn's disease study and its IND-enabling toxicology study. Collingwood ordered TSO meeting CGMP requirements from Ovamed for both of these studies in July 2006. Ms. Weinberger made it clear to you in July both orally and via e-mail that first doses in these two studies were intended to commence on September 1 (IND-enabling toxicology study) and December 4 (Phase 2a Crohn's disease study).

Pursuant to Section 2.1 of the MSA, Ovamed is required to supply Collingwood with TSO in accordance with Collingwood's specifications. Additionally, Section 5.1 of the MSA requires Ovamed to deliver TSO "manufactured in compliance with CGMP and all other applicable regulatory and governmental regulations..." You have indicated verbally that CGMP material will not be available before the end of December 2006. Moreover, representatives of Dr. Falk have indicated that they do not expect Ovamed to be in position to produce TSO meeting CGMP requirements before the middle of 2007 and perhaps later. Despite repeated requests, Ovamed has failed to deliver a written corrective action plan regarding a timetable and actions to be taken in response to the EMBA review of June 2, 2006, which led to the inability of Ovamed to supply TSO meeting CGMP requirements. It is now clear to our client that Ovamed is currently unable to supply it with TSO meeting CGMP requirements and that such inability to supply will continue for the foreseeable future.

As to Ovamed's objection that all orders by Collingwood require a purchase order, we refer you to the agreement between Ovamed and Collingwood that an e-mail requesting supply of product would constitute an adequate and sufficient purchase order. This agreement was reached in face-to-face meetings in May and has been subsequently confirmed in conference calls and via e-mail correspondence.

2. Ovamed's Continued Sale of TSO in the Collingwood Territory

Ovamed's continued sale of TSO worldwide to physicians via the Ovamed website constitutes an infringement of the patent rights licensed to Collingwood pursuant to Article 2.1 of the SLA which grant Collingwood the exclusive license to "make, have made, use, have used, lease, import, offer to sell, sell and/or have sold" the patent rights the United States, Canada, Japan and Australia.

Furthermore, we believe that Ovamed's internet sales of TSO to individuals in the United States for the purpose of administering TSO to individuals in the United States are in violation of at least two Federal laws of the United States regulating the sale of biological products and drugs in the United States. This position has been confirmed to our client in August 2006 by the written opinion of FDA counsel.

### III. Invoice Sent on July 6, 2006 Concerning Patent Costs

On April 10, 2006 Collingwood wired funds to Ovamed to cover all of the patent costs owed by Collingwood to Ovamed under the SLA for further payment to UIRF under the License Agreement. The July 6, 2006 invoice delivered to Collingwood by Ovamed appears to duplicate these previously paid patent costs and it is for this reason that no further payment has been made by Collingwood to Ovamed. Moreover, according to correspondence from the UIRF, Ovamed has not used Collingwood's April 10, 2006 payment to Ovamed to reimburse UIRF for the patent costs owed to UIRF by Ovamed under the License Agreement. Based on these facts, Collingwood demands an immediate accounting of the funds wired to Ovamed on April 10, 2006 and herewith explicitly reserves its rights to claim for a repayment of such funds.

### IV. Collaboration Agreement with Dr. Falk

Collingwood is in the process of negotiating a collaboration agreement with Dr. Falk for the development of TSO in shared fields. The current negotiations are centered around Dr. Falk's concern about receiving reimbursement from Collingwood of its pre-existing expenses in funding Ovamed. Collingwood's current position is that it cannot agree to pay for previous development work without first knowing what the expenses were and what work was done, information that has not been provided to Collingwood to date. We are hopeful we will be able to resolve this and other issues so that an agreement can be finalized. We note, however, that the contractual relationship between Collingwood and Dr. Falk is not relevant to the issues raised in this letter and does not affect the Contracts.

### V. Efforts to Commercialize TSO

Collingwood has used, uses and will use its best efforts to develop and commercialize TSO products in accordance with its obligations under the Contracts since this reflects both parties' interest. Our client strongly disagrees with your assertion that Collingwood has not been actively engaged in development and commercialization efforts for TSO. As noted above and on behalf of Collingwood, Paramount has established a TSO Development Team, led by Ms. Weinberger and consisting of clinical, regulatory, product development, toxicology, commercial, biostatistics, and project management personnel. The TSO Development Team conducts all of the strategic and tactical functions regarding the development of TSO.

For the record, we would like to highlight briefly some of the major activities of the TSO Development team to date:

1. Non-Clinical Development

The TSO Development Team and its toxicology consultants have reviewed the existing data and the relevant literature. A final draft IND-enabling toxicology protocol has been developed. Proposals were received from several toxicology labs for the conduct of this study. The TSO Development Team selected Laboratory of Pharmacology and Toxicology GmbH & Co. KG to conduct this study. Additionally, the Paramount team and its toxicology consultants have generated an overall toxicology plan for TSO to first marketing application.

2. Regulatory

Because published clinical studies exist with TSO, the TSO Development Team explored the potential regulatory strategy of utilizing the "notification regulatory mechanism" available in Australia to initiate a clinical trial with TSO in Crohn's disease. With this regulatory strategy, Collingwood would be in the clinic sooner in Australia than in the United States. The US FDA requires an IND-enabling toxicology study before clinical trials are allowed to begin under an IND in the United States. CGMP clinical trial material is required for clinical trials in Australia.

3. Clinical Development

The TSO Development Team has retained Novotech (a CRO in Australia) to conduct the Phase 2a Crohn's disease study. Novotech has completed its feasibility assessment for the study and has identified approximately 20 sites in Australia and New Zealand to conduct the study. Confidentiality agreements have also been entered into with various doctors interested in exploring applications for TSO in the fields of Crohn's disease, multiple sclerosis and asthma.

4. Commercial

Collingwood has generated a commercial plan for world wide development of TSO.

Despite all of this developmental and commercialization activity, further development requires the active support of Ovamed, particularly with regard to the supply of TSO meeting CGMP requirements. The significant delay in the supply of TSO meeting CGMP requirements by Ovamed and the overall uncertainty as to when such supply will commence severely impacts the development timeline for TSO. Collingwood has requested on numerous occasions a written corrective action plan (along with timelines) in regard to the actions to be taken in response to the EMEA requirements. However, Ovamed has failed to deliver a written corrective action plan in response to these requests.

VI. Final Remarks

Collingwood is, and continues to be, interested in further cooperation and collaboration with Ovamed. The existing issues outlined above are due to reasonable concerns that Ovamed may not be in a position to supply TSO meeting CGMP requirements to Collingwood as provided in the Contracts. The main question remains whether Ovamed can fulfill its obligations and will manufacture and supply TSO meeting CGMP requirements in accordance with the required timelines.

Collingwood remains hopeful that Ovamed can address these concerns in a satisfactory way and allow its relationship with Collingwood to move forward.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. F. Wetzler', with a stylized flourish at the end.

Christoph F. Wetzler

cc: J. Jay Lobell  
Lindsay A. Rosenwald, M.D.,  
Bertrand C. Liang, M.D.  
Frank Taffy  
Pamela K. York (UIRF); Executive Director  
Zev Sunleaf (UIRF); Senior Licensing Associate  
Klaus Lodigkeit, Vorberg Rechtsanwälte